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EXAMINER

RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
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3761

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11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/018,242

Applicant(s)

ASLIN ET AL.

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of the priority papers from the International Bureau.

### *Drawings*

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the medical injector must be shown or the feature(s) canceled from the claim(s). *No new matter should be entered.*
3. The drawings are objected to because in FIG 17 the reference character "314" is missing a lead line.
4. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

5. The disclosure is objected to because the applicant has used sixth paragraph, means-plus-function language to define the invention. Specifically, in claim 1 the applicants recite "means for activating said canister to open and dispense said medicament"; and in claim 38, the applicants recite "means for moving the mouth piece from a rest/protected position".
6. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element.

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7. The MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)". See also MPEP 2181 (Rev. 1, Feb.2000)).

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors.

9. Upon initial review it is noted that it appears that the applicants use the wrong set of reference numerals in the discussion of FIGS 15 and 16 where it appears that the applicants intend to use the reference numerals 250, 252, 253 and 254 rather than 50, 52, 53 and 54. See page 29, lines 14-28. Similarly, the applicants refer to a moveable plate 68 in line 1 of page 30, and arm 67 in line 29 of page 30. It appears that the applicants intend to use the reference numerals 268 and 267.

10. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

11. Claims 3 and 6-8 are objected to because of the applicants have recited "first spring means, which is later referred to as "pressure spring means" and second spring means later referred to as "return spring means". To increase the clarity of the claims the applicants should choose one term to describe a feature and consistently refer to the same term rather than introduce alternative terminology into the claims.

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12. Claims 20 and 21 are objected to because the applicant appears to be reciting the device defined in claim 10. However the applicants have used the article “a” to introduce the device. For clarity’s sake the applicants should amend the claims to recite “the device according to claim 10”.

13. In claims 25-31, the applicants introduce “a container” in addition to the canister recited in claim 1. It appears that the applicants are actually referring to the canister recited in claim 1 as a container since the specification does not describe a combination canister and container arrangement and the text associated with the character parenthetically referred to in claim 32 as the container (410) actually refers to the canister that contains medicament. The applicants should amend the claims to make it clear that claim 32 actually refers to the canister containing medicament rather than an additional container, if accurate.

14. Claims 1-44 are objected to because the applicant has evoked sixth paragraph, means-plus-function language to define the invention. Therefore the examiner objects to the claims for the reasons set forth above in the objection to the specification.

15. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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18. In claim 1 the applicants recite "return means for deactivating said canister to close it". It is unclear what specific combination of features the applicants are referring to as "it".

Accordingly, claim 1 is indefinite. Claims 2-44 incorporate the indefiniteness of claim 1.

19. In claim 7 recites the limitation "said spacer means" in line 11. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether the applicants are referring to a feature previously introduced using alternative language or are reciting an additional limitation in the claim. Claim 8 incorporates the indefiniteness of claim 7.

20. Also in claim 8, the applicants recite "the return means is arranged to said support means". It is unclear from this clause how the return means is arranged in relation to the support means.

21. Similarly in claim 10, the applicants recite, "a locking means arranged to the actuating means". It is unclear what particular arrangement the applicant is attempting to recite in this portion of the claim. Claims 11-21 incorporate the indefiniteness of claim 10.

22. In addition, in claim 17, the applicants recite "it is arranged in a medical injection device". It is unclear what combination of features the applicants are referring to as "it".

23. In claim 18, the applicants recite "there are arranged several devices". It is unclear what combination of features is being referred to as a "device". In claim 19 the applicants similarly recite first and second devices.

24. In claim 22, the applicants recite "a movement means connected to the actuating means and arranged such in the inhaler that it is moved by inhalation through the inhalation opening". It is unclear from the clause how the actuating means is arranged. In addition it is unclear what

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combination of features is being referred to as "it". Claims 23 and 24 incorporate the indefiniteness of claim 22.

25. The applicants repeatedly use the term "it" to refer to various features previously recited in the claims. When the applicants do so it is unclear what combination of features are being referred to as "it".

26. *Moreover the claims are generally narrative and fail to conform to current U.S. practice.* Accordingly, the applicants are required to review the claims in their entirety and make appropriate amendments to put the claims into a form conforming to current U.S. practice.

***Claim Rejections - 35 USC § 101***

27. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

28. Claims 34-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

29. The claims recite an apparatus that includes, or is attached to a part of the human body. For example, in claim 34 the applicants recite "the user operated means comprises parts of a hand of a user of the inhaler". Accordingly, the claims are directed to non-statutory subject matter. 1077 OG 24 (April 21, 1987). Claims 35-37 include the subject matter of claim 34.

***Claim Rejections - 35 USC § 102***

30. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

31. Claims 1-6, 9 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,347,998 to *Hodson et al.*

32. *Hodson et al* discloses a metered-dose, breath-actuated inhaler including all of the features recited in the claims. For example, the embodiment described with reference to FIGS 6-9 includes means for activating a canister to dispense medication in the form of cocking spring/first spring/pressure spring means (86) and vane (88), and return means comprising a spring/second spring means/return spring means (99) that biases the rocker element (90) to a position that prevents activation of the canister when inhalation terminates. See, e.g., column 6, lines 12-27.

33. With respect to claim 9, *Hodson et al* disclose monitoring means capable of detecting the time between activation and deactivation of the canister. See, e.g., column 3, lines 60-68.

34. With respect to claim 32, *Hodson et al* disclose a safety means that prevents activation of the inhaler when the safety means is in a non-operative state. The safety means takes the form of a timing mechanism associated with the priming mechanism for the inhaler. See, e.g., column 7, lines 34-48.

### ***Claim Rejections - 35 USC § 103***

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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36. Claims 38, 39 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5,347,998 to *Hodson et al* in view of US patent no. 3,151,618 to *Wakeman*.

37. *Hodson et al* disclose all of the features recited in claims 38, 39 and 41-44 without expressly disclosing means for moving the mouthpiece from a rest position where the mouthpiece is arranged substantially within a body to an activated position where at least the front end of the mouthpiece protrudes from the body of the inhaler.

38. However means for moving the mouthpiece were known at the time of invention. For example, US patent no. 3,151,618 to *Wakeman* discloses a canister-type inhaler that includes a mouthpiece (30) that pivots from a position within body of the inhaler FIG 1 to a position where the mouthpiece protrudes from the inhaler. See FIGS 1-4.

39. The mouthpiece (30) is held in the two positions by fixating means comprising a cap (12) and a surface (52) of the actuator against which the nozzle rests in the protruding position.

40. As seen in FIGS 1-4, the mouthpiece pivots about a pivot axis along pin (34) that is journaled in opening (36). The actuator (18) acts as a guide means limiting sliding movement of the mouthpiece along a longitudinal direction. The cap (12) handles/covers the actuating means (18) that set the inhaler ready for delivery of a dose of medication.

41. At the time of invention it would have been obvious to one with ordinary skill to modify the inhaler taught by *Hodson et al* to include a pivoting mouthpiece and cap arrangement as taught by *Wakeman* in order to make the inhaler more compact and less conspicuous when not in use. See, e.g., *Wakeman*, column 1, lines 35-39.

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***Allowable Subject Matter***

42. Claims 7, 8, 10-31, 33-37 and 40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action (without broadening the scope of the claims), and to include all of the limitations of the base claim and any intervening claims.

***Additional Pertinent Prior Art***

43. The following documents are considered pertinent to the applicant's invention: US patent nos. 5,119,806 to *Palson et al*, 5,447,150 to *Bacon*, 3,456,644 to *Thiel*, 5027808 to *Rich et al*, 5,069,204 to *Smith et al* and 5,826,571 to *Casper et al*.

***Contact Information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR



  
**GLENN K. DAWSON  
PRIMARY EXAMINER**